


Initially, Applicants wish to thank Primary Examiner Dvorak for the courtesy extended to applicants' representatives during the personal interview conducted on November 16, 1998. During such interview, Applicants' representatives discussed the significant shortcomings associated with the prior art proposed by the Examiner, as well as the specific instances where Applicants' specification and claims define over the prior art. Specifically, the Official Action first rejects independent claims 15 and 28, and dependent claims 10, 17, 18, 24, 27, 29-31 and 35 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. Applicants have deleted claims 28-35 and amended claims 10, 15 and 24 to overcome the Examiner's rejection. Accordingly, reconsideration and withdrawal of the rejection of claims 10, 15 and 24 under 35 U.S.C. §112, first paragraph is in order and respectfully requested. Also, Applicants respectfully submit that dependent claims 17, 18 and 27 are likewise allowable in that they ultimately depend on allowable base claims.


The Official Action next rejects independent claims 1, 15 and 28 and dependent claims 13 and 16 under §102(b) as being anticipated by U.S. Patent 4,289,122 to Mason et al (hereinafter Mason '122). According to the Examiner, Mason '122 shows a method of forming a foot orthosis comprising the step of vacuum sealing a thermoplastic sheet around a positive mold of an extremity so that the thermoplastic sheet and other thermoplastic material combine together. In response, independent claims 1 and 15 have been amended to clarify the distinctions of the present invention



over the prior art. As a result, it is respectfully requested that independent claims 1 and 15 (and all claims dependent thereon) are neither anticipated by, nor rendered obvious in view of Mason '122, or any other reference of record.

The present invention as recited in newly amended independent claims 1 and 15 is directed to an apparatus and method of forming a foot orthosis comprising the steps of positioning a strip of heated thermoformable copolymer material around predetermined locations on a positive mold and then draping another heated sheet of thermoformable copolymer material around the positive mold without disturbing the previously placed thermoformable material so that the two materials bond together to provide increased strength and rigidity.

Mason '122 fails to anticipate the present invention as recited in newly amended independent claims 1 and 15 for the following reasons. Admittedly, Mason '122 discloses a method of forming a foot orthosis comprising the step of vacuum sealing a thermoplastic sheet around a positive mold of an extremity so that the inside surface of orthosis will intimately match the outline of a patient's foot and leg. However, Mason '122 fails to disclose the method whereby a thermoplastic sheet bonds to other thermoplastic material to provide additional strength. In fact, Mason '122 teaches away from the method disclosed in the present application by suggesting that in forming the device, a first portion of thermoformable material is placed next to a positive mold of the extremity under a stocking. A second, heated sheet of thermoformable material is then draped over the stocking, vacuum sealed and then cut.



Once the second sheet of material cools, the two separate pieces (greave 2 and plantar section 3) of thermoformable material are removed from the positive mold before being coupled together with the use of two rivets 10. In actuality, the purpose of placing the first sheet under a stocking with the second heated sheet draped over the stocking is to provide a perfect fit between the foot and leg section at an overlapping area of the two sections not to bond the two materials together. See *Mason '122* at Column 3, line 49 - Column 4, line 1. Thus, since *Mason '122* fails to disclose a feature clearly recited in newly amended independent claims 1 and 15, that is, a method of forming a foot orthosis wherein a thermoplastic sheet bonds to other thermoplastic material, *Mason '122* simply could not, and does not, anticipate the present invention as recited in newly amended independent claims 1 and 15.

Accordingly, withdrawal of the present rejection of independent claims 1 and 15 as being anticipated by *Mason '122* is respectfully requested. Likewise, dependent claims 13 and 16 are similarly believed to be allowable in that they depend from what is believed to be allowable base claims.

Independent claims 15 and 28, and dependent claims 16 and 27 are rejected under §102(b) as being anticipated by U.S. Patent 4,938,777 to *Mason* (hereinafter *Mason '777*). By this amendment, independent claim 15 has been amended to clarify the distinctions of the present invention over the *Mason '777* reference, and independent claim 28 has been cancelled. As a result, it is believed that independent claim 15 and dependent claims 16 and 27 are neither anticipated by, nor rendered



obvious in view of the Mason '777 reference.

With respect to newly amended independent claim 15, Mason '777 fails to anticipate the present invention as defined for all the reasons set forth hereinabove with respect to the reasons Mason '122 fails to anticipate the invention of claims 1 and 15. That is, Mason '777 nowhere suggests a method of forming a foot orthosis wherein a thermoplastic sheet bonds to other thermoplastic material to provide increased strength and rigidity. In fact, a careful reading of the Mason '777 reference reveals that the increased strength and rigidity of the Mason '777 reference is obtained by securing the lower sections of a rib to the inner side of a cup by any convenient fastening means, such as adhesive or rivets. See *Mason '777* at Column 5, lines 13-17. Another embodiment of Mason '777 suggests that the entire rib is formed of a single piece of material so that there is no joint line. See *Mason '777* at Column 4, lines 38-41.

However, in light of the fact that Mason '777 discloses that lower portions of the rib will be molded or formed as thicker portions in the walls of the cup, Applicants have also cancelled claims 28-37 which disclose a method of forming a foot orthosis wherein injection molding is utilized to provide increased support for the device at predetermined locations. Accordingly, withdrawal of the present rejection of independent claim 15 and dependent claims 16 and 27 as being anticipated by Mason '777 is respectfully requested.


For the reasons articulated above, Applicant respectfully requests therefor that

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the rejection be withdrawn and favorable reconsideration be given. If any further discussion about this case would be beneficial, the Examiner is invited to contact the undersigned.

Respectfully submitted,



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